

11-23-04

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Dated: November 22, 2004

Signature: Linda Blake
(Linda Blake)

Docket No.: GLYO-P03-002
(PATENT)



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Chang et al.

Confirmation No.: 9375

Application No.: 10/657383

Art Unit: 1623

Filed: September 8, 2003

Examiner: Not Yet Assigned

For: METHOD FOR ENHANCING THE
EFFECTIVENESS OF CANCER
THERAPIES

November 22, 2004

THIRD SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT (IDS)

MS Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement is filed before the mailing date of a first Office Action on the merits as far as is known to the undersigned (37 CFR 1.97(b)(3)). Accordingly, Applicants believe no fee is due with this submission.

A copy of each reference on the PTO/SB/08 is attached, except the U.S. patents.

In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists. In accordance with 37 CFR 1.97(h), the filing of this Information Disclosure statement shall not be construed to be an admission that any patent,


publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

It is submitted that the Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 18-1945, under Order No. GLYO-P03-002. A duplicate copy of this paper is enclosed.

Dated: November 22, 2004

Respectfully submitted,

By 

Erika Takeuchi

Registration No.: 55,661

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PTO/SB/21 (09-04)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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TRANSMITTAL FORM (to be used for all correspondence after initial filing)	Application Number	10/657383	
	Filing Date	September 8, 2003	
	First Named Inventor	Yan Chang	
	Art Unit	1623	
	Examiner Name	Not Yet Assigned	
Total Number of Pages in This Submission	11	Attorney Docket Number	GLYO-P03-002

ENCLOSURES (Check all that apply)

<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Reply to Missing Parts/ Incomplete Application <input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____ <input type="checkbox"/> Landscape Table on CD	<input type="checkbox"/> After Allowance Communication to TC <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please Identify below): S/B 08 (5 pages) Copy of references BE, CS-CP3 Return Receipt Postcard
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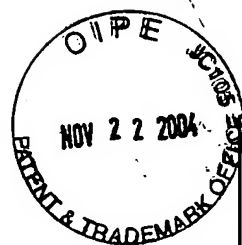
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Signature			
Printed name	Erika Takeuchi		
Date	November 22, 2004	Reg. No.	55,661

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Substitute for form 1449A/B/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet	1	of	5	Attorney Docket Number	GLYO-P03-002
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Complete if Known

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Attorney Docket Number	GLYO-P03-002

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	AI	US-6,274,566	08-14-2001	Eliasz et al.	
	AJ	US-6,680,306	01-20-2004	Chang et al.	
	AK	US-2002/0107222	08-08-2002	Platt	
	AL	US-2003/0064957	04-03-2003	Klyosov et al.	
	AM	US-6,500,807	12-31-2002	Platt et al.	
	AN	US-6,258,383 B1	07-10-2001	Gohlke et al.	
	AO	US-5,831,052	11-03-1998	Hillman et al.	
	AP	US-5,498,702	03-12-1996	Mitchell et al.	

FOREIGN PATENT DOCUMENTS

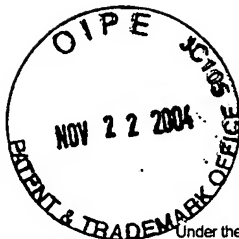
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
	BE	WO 03/000118	06-21-2002	Chang et al.		

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	CS	APARICIO, A. In vitro cytoinductive effects on multiple myeloma cells induced by bisphosphonates. Leukemia 12, 220-229 (1998).	
	CT	BOLD, R.J. et al. Chemosensitization of Pancreatic Cancer by Inhibition of the 26S Proteasome. J. Surg. Res. 100, 11-17 (2001).	
	CU	BREWER, C.F. Binding and cross-linking properties of galectins. Biochim. Biophys. Acta 1572, 255-262 (2002).	
	CV	BURKE, P.A. et al. Combined Modality Radioimmunotherapy. Cancer 94, 1320-1331 (15 Feb. 2002).	
	CW	CAMBY, I. et al. Galectins are differentially expressed in supratentorial pilocytic astrocytomas, astrocytomas, anaplastic astrocytomas and glioblastomas, and significantly modulate tumor astrocyte migration. Brain Pathology 11, 12-26 (2001).	
	CX	CHERAYIL, B.J. et al. Molecular cloning of a human macrophage lectin specific for galactose. PNAS 87, 7324-7328 (Sept. 1990).	
	CY	CHOUFANI, G. et al. The Levels of Expression of Galectin-1, Galectin-3, and the Thomsen-Friedenreich Antigen and Their Binding Sites Decrease as Clinical Aggressiveness Increases in Head and Neck Cancers. Cancer 86, 2353-2363 (1 Dec. 1999).	
	CZ	CINDOLO, L. et al. Galectin-1 and Galectin-3 Expression in Human Bladder Transitional-Cell Carcinomas. Int. J. Cancer 84, 39-43 (1999).	
	CA1	COOPER, D.N.W. Galectinomics: finding themes in complexity. Biochim Biophys Acta 1572,	

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Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	10/657,383
				Filing Date	September 8, 2003
				First Named Inventor	Yan Chang
				Art Unit	1623
				Examiner Name	Not Yet Assigned
Sheet	2	of	5	Attorney Docket Number	GLYO-P03-002

		209-231 (2002).	
CB1		DANGUY, A. et al. Galectins and cancer. Biochim. Biophys Acta 1572, 285-293 (2002).	
CC1		DEL BINO, G. et al. Altered Susceptibility of Differentiating HL-60 Cells to Apoptosis Induced by Antitumor Drugs. Leukemia 8, 281-288 (Feb. 1994).	
CD1		DIPAOLA, R.S. and Aisner, J. Overcoming bcl-2- and p53-Mediated Resistance in Prostate Cancer. Seminars in Oncology 26, 112-116 (Feb. 1999).	
CE1		EASTMAN, A. and Rigas, J.R. Modulation of Apoptosis Signaling Pathways and Cell Cycle Regulation. Seminars in Oncology 26, 7-16 (Oct. 1999).	
CF1		FAN, W. et al. In vitro evaluation of combination chemotherapy against human tumor cells. Oncology Reports 5, 1035-1042 (1998).	
CG1		FRANCOIS, C. et al. Galectin-1 and Galectin-3 Binding Pattern Expression in Renal Cell Carcinomas. Am. J. Clin. Pathol. 112, 194-203 (1999).	
CH1		GRANT, S. and Dent, P. Rational integration of agents directed at novel therapeutic targets into combination chemotherapeutic regimens. Curr. Opin. Investigational Drugs 2, 1600-1605 (2001).	
CI1		GROSS, A. The role of BCL-2 family members in apoptosis. Published by the Department of Biological Regulation, Weizmann Institute of Science, Israel.	
CJ1		HARA, I. et al. Sodium butyrate induces apoptosis in human renal cell carcinoma cells and synergistically enhances their sensitivity to anti-Fas-mediated cytotoxicity. Int. J. Oncol. 17, 1213-1218 (2000).	
CK1		HERNANDEZ, J.D. and Baum, L.G. Ah, sweet mystery of death! Galectins and control of cell fate. Glycobiology 12, 127R-136R (2002).	
CL1		HORTOBAGYI, G.N. Recent Progress in the Clinical Development of Docetaxel (Taxotere). Seminars in Oncology 26, 32-36 (June 1999).	
CM1		HRDLICKOVA, E. et al. Detection of galectin-3 in tear fluid at disease states and immunohistochemical and lectin histochemical analysis in human corneal and conjunctival epithelium. Br. J. Ophthalmol. 85, 1336-1340 (2001).	
CN1		INOHARA, H. et al. Expression of Galectin-3 in Fine-Needle Aspirates as a Diagnostic Marker Differentiating Benign from Malignant Thyroid Neoplasms. Cancer 85, 2475-2484 (1 June 1999).	
CO1		INUFUSA, H. et al. Role of galectin-3 in adenocarcinoma liver metastasis. Int. J. Oncol. 19, 913-919 (2001).	
CP1		JENSEN-JAROLIM, E. et al. Anti-Galectin-3 IgG Autoantibodies in Patients with Crohn's Disease Characterized by Means of Phage Display Peptide Libraries. J. Clin. Immunol. 21(5), 348-356 (2001).	
CQ1		JOHNSON, K. R. et al. Antagonistic Interplay between Antimitotic and G ₁ -S Arresting Agents Observed in Experimental Combination Therapy. Clin. Cancer Res. 5, 2559-2565 (Sept. 1999).	
CR1		JULIAO, S. et al. Galectin-3: A Marker and Diagnostic Aid for Chordoma. Present at the 47 th Annual Meeting, Orthopaedic Research Society, February 25-28, 2001, San Francisco, CA.	
CS1		KARMANOS, Barbara Ann Cancer Institute. Novel Therapeutic Targets & Therapies. www.karmanos.org/we/research/prostate/novel.html retrieved on 1/27/2003.	
CT1		KILPATRICK, D. C. Animal Lectins: a historical introduction and overview. Biochim. et Biophys. Acta 1572, 187-197 (2002).	
CU1		KIM, R. et al. A pitfall in the survival benefit of adjustment chemotherapy for node- and hormone receptor-positive patients with breast cancer: The paradoxical role of Bcl-2 oncoprotein (Review). Int. J. Oncol. 19, 1075-1080 (2001).	
CV1		KLASA, R. J. et al. Eradication of Human Non-Hodgkin's Lymphoma in SCID Mice by BCL-2 Antisense Oligonucleotides Combine with Low-Dose Cyclophosphamide. Clin. Cancer Res. 6, 2492-2500 (June 2000).	

Examiner Signature		Date Considered	
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Sheet	3	of	5	Attorney Docket Number	GLYO-P03-002

	CW1	LEFFLER, H. et al. Specificity of Binding of Three Soluble Rat Lung Lectins to Substituted and Unsubstituted Mammalian B-Galactosides. J. Biol. Chem. 261(22), 10119-10126 (5 Aug. 1986).	
	CX1	LIM, Y. et al. Identification of autoantibodies associated with systemic lupus erythematosus. Biochem. Biophys. Res. Comm. 295, 119-124 (2002).	
	CY1	LINEHAN, W. M. Inhibition of Prostate Cancer Metastasis: a Critical Challenge Ahead. J. Nat. Cancer Inst. 87(5), 331-332 (1 March 1995).	
	CX1	LIU, F.-T. et al. Intracellular functions of galectins. Biochim et Biophys Acta 1572, 263-273 (2002).	
	CA2	LOPES DE MENEZES, D. E. et al. Molecular and Pharmacokinetic Properties Associated with the Therapeutics of Bcl-2 Antisense Oligonucleotide G3139 Combined with Free and Liposomal Doxorubicin. Clin. Cancer Res. 6, 2891-2902 (July 2002).	
	CB2	LOTZ, M. M. et al. Decreased expression of Mac-2 (carbohydrate binding protein 35) and loss of its nuclear localization are associated with the neoplastic progression of colon carcinoma. PNAS 90, 3466-3470 (April 1993).	
	CC2	MAJLESSIPOUR, F. The Combination Regimen of Idarubicin and Taxotere is Effective Against Human Drug-resistant Leukemic Cell Lines. Anticancer Res. 22, 1361-1368 (2002).	
	CD2	MATARRESE, P., et al. Galectin-3 overexpression protects from cell damage and death by influencing mitochondrial homeostasis. FEBS Letters 473, 311-315 (2000).	
	CE2	MATARRESE, P., et al. Galectin-3 Overexpression Protects from Apoptosis by Improving Cell Adhesion Properties. Int. Cancer 85, 545-554 (15 Feb. 2000).	
	CF2	MEY, A. et al. Expression of the galactose binding protein Mac-2 by human melanoma cell-lines. Cancer Letters 81, 155-163 (1994).	
	CG2	NAKAMURA, M. et al. Involvement of galectin-3 expression in colorectal cancer progression and metastasis. Int. J. Oncol. 15, 143-148 (1999).	
	CH2	NANGIA-MAKKER, P. et al. Inhibition of Human Cancer Cell Growth and Metastasis in Nude Mice by Oral Intake of Modified Citrus Pectin. J. Nat. Cancer Inst. 94(24) 1854-1862 (18 Dec. 2002).	
	CI2	NOVOCASTRA LABORATORIES, LTD. Galectin-3: mouse monoclonal antibody NCL-GAL3.	
	CJ2	OHANNESIAN, D. W. et al. Carcinoembryonic Antigen and Other Glycoconjugates Act as Ligands for Galectin-3 in Human Colon Carcinoma Cells. Cancer Res. 55, 2191-2199 (15 May 1995).	
	CK2	ONCOLINK: LILLY ONCOLOGY TREATMENT OPTIONS. www.oncolink.com/treatment/section.cfm retrieved on 2/12/2003.	
	CL2	ORLANDI, F. et al. Galectin-3 Is a Presurgical Marker of Human Thyroid Carcinoma. Cancer Res. 58, 3015-3020 (15 July 1998).	
	CM2	PERILLO, N. L. Galectins: versatile modulators of cell adhesion, cell proliferation, and cell death. J. Mol. Med. 76, 402-412 (1998).	
	CN2	PIENTA, K.J. et al. Inhibition of spontaneous metastasis in a rat prostate cancer model by oral administration of modified citrus pectin. J. Nat. Cancer Inst. 87(5), 348-353 (1 March 1995).	
	CO2	PLATT, D. and Raz, A. Modulation of the Lung Colonization of B16-F1 Melanoma Cells by Citrus Pectin. J. Nat. Cancer Inst. 84, 438-442 (18 March 1992).	
	CP2	PUGLIESE, G. The Diabetic Milieu Modulates the Advanced Glycation End Product-Receptor Complex in the Mesangium by Inducing or Upregulating Galectin-3 Expression. Diabetes 49, 1249-1257 (July 2000).	
	CQ2	RABINOVICH, G. A. et al. Recombinant Galectin-1 and Its Genetic Delivery Suppress Collagen-induced Arthritis via T Cell Apoptosis. J. Exp. Med. 190(3), 385-397 (2 Aug. 1999).	
	CR2	RABINOVICH, G. A. Role of galectins in inflammatory and immunomodulatory processes. Biochim. Biophys. Acta 1572, 274-284 (2002).	
	CS2	RABINOVICH, G. A. et al. The antimetastatic effect of a single low dose of cyclophosphamide	

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Sheet	4	of	5	Attorney Docket Number	GLYO-P03-002

		involves modulation of galectin-1 and Bcl-2 express. Cancer Immunol. Immunother. 50, 597-603 (2002).	
	CT2	RAYNAUD, F. I. Pharmacokinetics of G3139, a Phosphorothioate Oligodeoxynucleotide Antisense to bcl-2, after Intravenous Administration or Continuous Subcutaneous Infusion to Mice. J. Pharmacol. Exp. Therapeutics 281(1), 420-427 (1997).	
	CU2	RUDIN, C. M. et al. A pilot trial of G3139, a bcl-2 antisense oligonucleotide, and paclitaxel in patients with chemorefractory small-cell lung cancer. Ann. Oncol. 13, 539-545 (2002).	
	CV2	RUITER, G. A. et al. Alkyl-Lysophospholipids as Anticancer Agents and Enhancers of Radiation-Induced Apoptosis. Int. J. Radiation Oncol. Biol. Phys. 49(2), 415-419 (2001).	
	CW2	SANO, H. et al. Human Galectin-3 Is a Novel Chemoattractant for Monocytes and Macrophages. J. Immunol. 165, 2156-2164 (2000).	
	CX2	SAUER, G. et al. New Molecular Targets of Breast Cancer Therapy. Strahlenther. Onkol. 178(3), 123-133 (2002).	
	CY2	SHIH, C. et al. Cryptophycins: A Novel Class of Potent Antimitotic Antitumor Depsipeptides. Curr. Pharm. Des. 7, 1259-1276 (2001).	
	CZ2	SÖRME, P. et al. Low Micromolar Inhibitors of Galectin-3 Based on 3-Derivatization of N-Acetylactosamine. ChemBioChem 3, 183-189 (2002).	
	CA3	TAKAHASHI, T. et al. Mechanisms of the apoptotic activity of CI-F-araA in a human T-ALL cell line, CCRF-CEM. Cancer Chemother Pharmacol. 50, 193-201 (2002).	
	CB3	TENTORI, L. et al. Role of Wild-Type p 53 on the Antineoplastic Activity of Temozolomide Alone or Combined with Inhibitors of Poly(ADP-Ribose) Polymerase. J. Pharmacol. Exp. Therapeutics 285(2), 884-893 (1998).	
	CC3	TORTORA, G. et al. Combined Blockade of Protein Kinase A and Bcl-2 by Antisense Strategy Induces Apoptosis and Inhibits Tumor Growth and Angiogenesis. Clin. Cancer Res. 7, 2537-2544 (Aug. 2001).	
	CD3	TORTORA, G. et al. Protein Kinase A as Target for Novel Integrated Strategies of Cancer Therapy. Ann. N.Y. Acad. Sci. 968, 139-147 (2002).	
	CE3	TU, S.-M. et al. Combination adriamycin and suramin induces apoptosis in bcl-2 expressing prostate carcinoma cells. Cancer Letters 93, 147-155 (1995).	
	CF3	USUDA, J. et al. Increased Cytotoxic Effects of Photodynamic Therapy in IL-6 Gene Transfected Cells via Enhanced Apoptosis. Int. J. Cancer 93, 475-480 (2001).	
	CG3	VIVAT-HANNAH, V. et al. Synergistic Cytotoxicity Exhibited by Combination Treatment of Selective Retinoid Ligands with Taxol (Paclitaxel). Cancer Res. 61(24), 8703-8711 (15 Dec. 2001).	
	CH3	WU, X.-X. et al. Enhancement of Fas-mediated Apoptosis in Renal Cell Carcinoma Cells by Adriamycin. Cancer Res. 60, 2912-2918 (1 June 2000).	
	CI3	XIA, F. The molecular basis of radiosensitivity and chemosensitivity in the treatment of breast cancer. Semin. Radiat. Oncol. 12(4), 296-304 (2002).	
	CJ3	XU, X.-C. et al. Differential expression of galectin-1 and galectin-3 in benign and malignant salivary gland neoplasms. Int. J. Oncol. 17, 271-276 (2000).	
	CK3	YAMAMOTO, D. et al. Synergistic action of apoptosis induced by eicosapentaenoic acid and TNP-470 on human breast cancer cells. Breast Cancer Res. Treatment 55, 149-160 (1999).	
	CL3	YAMAOKA, K. et al. Overexpression of A β -Galactoside Binding Protein Causes Transformation of Balb3T3 Fibroblast Cells. Biochem. Biophys. Res. Comm. 179(1), 272-279 (30 Aug. 1991).	
	CM3	YAMAZAKI, K. et al. Simultaneous Induction of Galectin-3 Phosphorylated on Tyrosine Residue, p21 waf1/Cip1/Sdi1, and the Proliferating Cell Nuclear Antigen at a Distinctive Period of Repair of Hepatocytes Injured by CCl4. Biochem. Biophys. Res. Comm. 280, 1077-1084 (2001).	
	CN3	YANG, R.-Y. et al. Expression of galectin-3 modulates T-cell growth and apoptosis. PNAS	

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		93, 6737-6742 (June 1996).	
	CO3	YOSHII, T. et al. Galectin-3 Phosphorylation is Required for Its Anti-apoptotic Function and Cell Cycle Arrest. J. Biol. Chem. 277(9), 6852-6857 (1 March 2002).	
	CP3	ZENG, S. et al. In Vitro Evaluation of Schedule-dependent Interactions between Docetaxel and Doxorubicin against Human Breast and Ovarian Cancer Cell. Clin. Cancer Res. 6, 3766-3773 (Sept. 2000).	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

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